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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/714,792	11/16/2000	Mary Collins		3965

7590

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EXAMINER

PRASAD, SARADA C

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 06/25/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/714,792

Applicant(s)

COLLINS ET AL.

Examiner

Sarada C Prasad

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 May 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18 and 38-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 18 and 38-45 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment( )**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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***Formal Matters***

1. Applicants' preliminary amendments of Paper No. 4 1/2 (11/16/00) are acknowledged. As per applicants request, original claims 1-10, 19-25, 28-33, 36, and 37 have been cancelled. Applicants also requested cancellation of original claims 11-17, 26,27, 34, and 35, while adding new claims numbered 50-57 (the Paper No. 4 and 11/16/00 as well). This amendment has been entered and claims 11-17, 26,27, 34, and 35 have been cancelled, and new claims 50-57 have been added. With the cancellation of all the original claims requested to be cancelled, only claim 18 remains pending from the original claims.

The numbering of new claims (50-57) is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 50-57 have been renumbered as 38-45. Currently, claims 18, 38-45 are pending.

***Restriction/Election***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 18 and 41, each in part drawn to a composition comprising an antibody which specifically reacts with amino acid sequence of SEQ ID No. 2 or part of SEQ ID No. 2, and a method of inhibiting its interaction with its ligand, classified in class 514, sub class 4.

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Group II. Claims 18 and 41, each in part drawn to a composition comprising an antibody which specifically reacts with amino acid sequence of SEQ ID No. 4 or part of SEQ ID No. 4, and a method of inhibiting its interaction with its ligand, classified in class 514, sub class 4.

Group III. Claim 38 in part drawn to a screening method for identification of an inhibitor of binding of IL-13 to IL-13 receptor of SEQ ID No. 2, classified in class 435, subclass 7.1

Group IV. Claims 38, in part drawn to a screening method for identification of an inhibitor of binding of IL-13 to IL-13 receptor of SEQ ID NO. 4, classified in class 435, subclass 7.1

Group V. Claims 39-40, and 44, each in part drawn to a composition comprising inhibitor of binding of IL-13 to its receptor (SEQ ID No. 2), and a method of inhibiting such binding in a mammalian subject comprising administering a therapeutically effective amount of the same classified in class, subclass undeterminable.

Group VI. Claims 39-40, and 45, each in part drawn to a composition comprising inhibitor of binding of IL-13 to its receptor (SEQ ID No. 4), and a method of inhibiting such binding in a mammalian subject comprising administering a therapeutically effective amount of the same classified in class, subclass undeterminable.

Group VII. Claims 42-43, each in part drawn to a method of potentiating IL-13 activity said method comprising combining a protein having IL-13 activity with an isolated IL-13 receptor chain comprising the SEQ ID No. 2, classified in class 514, subclass 4.

Group VIII. Claims 42-43, each in part drawn to a method of potentiating IL-13 activity said method comprising combining a protein having IL-13 activity with an isolated IL-13 receptor chain comprising the SEQ ID No. 4, classified in class 514, subclass 4.

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These above inventions I-VIII are so grouped in order to have only one polypeptide of either SEQ ID No. 2 or No. 4 in each Group for examination purposes. Furthermore, no matter which Group the Applicant elects, the Applicant is required to specify one polypeptide for examination. This requirement is made under 1192 O.G.68 Notice (November 19, 1996), as examination of more than one sequence in one application would result in an undue burden on the PTO.

The inventions are distinct, each from the other because:

Inventions in Groups I, II and V, VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the compositions of the different inventions I-II and V-VI are intended to inhibit the interaction of IL-13 with its receptor either using antibody (Groups I, II), or a compound of unknown nature (V, VI). However antibodies of Groups I, II (for SEQ ID No. 2 and SEQ ID NO. 4) can be used for other purposes such as immunoassays, or diagnostic methods, while inhibition of IL-13 interaction with its receptor can be achieved by other means such as peptide analogs of IL-13 or IL-13 receptor as can be interpreted from Groups V-VI. Therefore, each of these inventions can be practiced without the use of the other.

Groups III-IV involving methods of screening for antagonists are distinct from either Groups I-II, directed to compositions of antibodies, or Groups V-VI directed to compositions of receptor antagonists of unknown nature.

Inventions I-II are related to inventions III-VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

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process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The antibody compositions of Groups I-II can be used for purification of the polypeptides, or as agonists or antagonists as in inventions III-VIII.

Additionally, Groups VII-VIII directed to potentiating the action of IL-13 are distinct from either groups V-VI involving methods of inhibiting IL-13 interactions with its receptor.

Having shown that these inventions are distinct for the reasons given above, they have acquired a separate status in the art shown by their different classification, and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has prima facie shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


### *Advisory Information*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarada C Prasad whose telephone number is 703-305-1009. The examiner can normally be reached Monday – Friday from 8.00 AM to 4.30 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sarada Prasad, Ph.D.  
Examiner  
Art Unit 1646  
June 7<sup>th</sup>, 2002

  
YVONNE EYLER, Ph.D.  
SUPERVISORY PATENT EXAMINER  
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